

Data Set Name: ad_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	ADSTDAT_INT	Num	8			ADSTDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	ADSTTIM	Char	15			ADSTTIM
4	ADWGHTX	Num	8		6.3	Dosing Calculation Weight (kg)
5	ADDOSEX	Num	8		6.2	Actual Dose Received (total ug)
6	ADROUTE_STD	Num	8		11.	Route of Administration (coded value)
7	ADNORSN_STD	Num	8		11.	If dose NOT received, code reason below... (coded value)

Data Set Name: *analy_is_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	STARTDT	Num	8			STARTDT_tmp (obscured as an interval in days from the reference date: Date of Birth)
2	ENDDT	Num	8			ENDDT_tmp (obscured as an interval in days from the reference date: Date of Birth)
3	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
4	ISCODE_STD	Num	8		11.	Iron Supp Codes (Coded Value)
5	ISTYPE_STD	Num	8		11.	Iron Type (Coded Value)
6	ISROUTE_STD	Num	8		11.	Route of Iron (Coded Value)
7	ISDOSE	Num	8		5.1	Dose (mg/kg)
8	STAT_NOTE	Char	100			Brief description of the imputation method

Data Set Name: *analy_lab_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	GASTRAT	Num	8			GA stratum at randomization
3	DOSE1_BRTH_DIFF	Num	8			Calculated days from birth to first study dose
4	WD_EXCLUDE	Num	8			Withdrew from protocol without consenting to further data report
5	SDYN	Char	3		\$3.	Study drug started
6	TREATMENT	Num	8			Treatment (1 = Darbepoetin)
7	SI_TIMEPT	Char	4			Study Indicated Lab Timepoint entered into DRB03 (not scrubbed)
8	DAYS_FROM_BIRTHX	Num	8			Calculated days from birth (used in analysis)
9	DAYS_FROM_BIRTH_CAT	Num	8			Calculated days from birth category (used in analysis)
10	WBCX	Num	8		6.1	WBC (corrected)
11	RBCX	Num	8		5.2	RBC
12	HEMOX	Num	8		5.1	Hemoglobin
13	HEMAX	Num	8		5.1	Hematocrit
14	HBRCMX	Num	8			Red Cell Mass
15	HBWGHTX	Num	8		6.3	Dosing Weight
16	HBSITE	Char	30		\$30.	Hgb/Hct site
17	HBSRC	Char	15		\$15.	Hgb/Hct source
18	MCVX	Num	8		11.	MCV
19	MCHCX	Num	8		5.1	MCHC
20	ANCX	Num	8		8.3	Absolute Neutrophil count
21	MATUR	Num	8		11.	Neutrophils: Mature (PMN/Seg)
22	BANDSX	Num	8		11.	Neutrophils: Bands
23	OTHIMMX	Num	8		11.	Neutrophils: Other immature forms
24	PLATX	Num	8		11.	Platelet Count
25	RETICX	Num	8		5.1	Retic Count
26	ABRETICX	Num	8		9.3	Absolute Retic Count
27	RETICHEMX	Num	8		6.1	Reticulocyte Hemoglobin
28	FERRX	Num	8		11.	Ferritin
29	IRONYN	Char	3		\$3.	Iron Supplementation Changed (y/n)
30	TOTBILX	Num	8		5.1	Total Bilirubin
31	DIRBILX	Num	8		5.1	Direct Bilirubin
32	RCM_TIMEPT	Char	4			RCM Lab Timepoint entered into DRB05 or DRB04 (not scrubbed)
33	FAMILYID	Num	8			Family ID

Data Set Name: *analy_sub_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	BIRTHORDER	Num	3			Birth order within the pregnancy
3	AGERANDHR	Num	8			Age at randomization
4	GASTRAT	Num	8			GA Stratum at randomization
5	TREATMENT	Num	8			Treatment (1 = Darbepoetin)
6	GESTAGE_WKDY	Num	8			Gestational age
7	BIRTHWTX	Num	8			Birth weight
8	HISP	Num	8			Biological Mother: Hispanic Origin
9	LBHEMABLX	Num	8			Baseline Hematocrit
10	ANTESTER	Num	8			Antenatal Steroids Administered
11	MULTBRTH	Num	8			Multiple Birth
12	OUTBORN	Num	8			Born outside of Neonatal Research Network hospital
13	RACE3	Num	8			Biological Mother: Race
14	SEX	Num	8			Sex
15	SGA	Num	8			Small for Gestational Age
16	CRDCLP_MLK	Num	8			Delayed cord clamping or milking
17	MEDUC3	Num	8			Biological Mother: Highest level of education
18	SDYN	Char	3		\$3.	Study drug started
19	WD_EXCLUDE	Num	8			Withdrew from protocol without consenting to further data report
20	SCCMPLTYN	Char	3		\$3.	Study drug completed as planned
21	ITT_DOSEWEEKS	Num	8			Total weeks expected to receive study drug (from randomization to 36 weeks PMA or death/discharge if earlier)
22	DOSEWEEKS	Num	8			Total weeks actually received study drug
23	SUMDOSE	Num	8			Total dosage of study drug recorded
24	TOTAL_GT2DAYS_FROM_PLANX	Num	8			Total weeks study drug was more than 2 days early or late
25	MEANDOSE	Num	8			As Treated: Average dose of study drug per week
26	ITT_MEANDOSE	Num	8			ITT: Average dose per week
27	PERCENT_IV	Num	8			Percent of study drug doses administered via IV
28	PERCENT_DOSES_COMPLETEDX	Num	8			Percent of study drug doses administered of doses expected
29	IRON_REC	Char	19			Type of iron received during protocol period
30	PARIRON_WEEKSX	Num	8			Weeks received parenteral iron
31	PARIRON_SUMDOSEX	Num	8			Total parenteral iron recorded
32	PARIRON_MEANDOSEX	Num	8			Average parenteral iron recorded per week

Num	Variable	Type	Len	Format	Informat	Label
33	ORALIRON_WEEKS	Num	8			Weeks received oral iron
34	ORALIRON_SUMDOSEX	Num	8			Total oral iron recorded
35	ORALIRON_MEANDOSEX	Num	8			Average oral iron recorded per week
36	NOIRON_WEEKSX	Num	8			Total weeks iron held or skipped
37	EVERTRANS	Num	8			Ever transfused (Tfcount > 0)
38	TFCOUNTX	Num	8			Total Transfusions
39	TFSUMVOL_PER_KGX	Num	8			Total volume per kg weight transfused (if transfused)
40	TFAVEVOL_PER_KGX	Num	8			Average volume per kg weight transfused, per transfusion (if transfused)
41	TFPTPX	Num	8			Total Transfusions administered per Study's Transfusion Protocol
42	DONORCOUNTX	Num	8			Count of Unique Donor Exposures
43	A_SEPSIS_CULTPOS	Num	8			Any culture-positive sepsis event
44	A_STUDY_AE	Num	8			Any other study-monitored AE, or other unexpected event that is possibly related to the study or results in death, occurring with moderate+ severity
45	SAE_COUNTX	Num	8			Count of serious adverse events during the protocol period
46	SAE	Num	8			Any serious adverse event during the protocol period
47	DEATH_DISCH	Num	8			Death by discharge
48	HOSPSTAYX	Num	8			Length of hospital stay
49	ROP_TOP	Char	10			Retinopathy of Prematurity (ROP) Stage 3 or Treatment
50	ROPSTAGE3	Char	10			ROP stage 3
51	ROPMED	Char	10			Medical treatment for ROP (Avastin, anti-VEGF drug, O2 SATS)
52	BPD_PRAGSEV	Char	10			Bronchopulmonary Dysplasia grades 2 or 3 (see documentation)
53	IVH	Char	10			Intraventricular Hemorrhage, grade II or higher
54	IVHGR1PLUS	Char	10			Intraventricular Hemorrhage, grade I or higher
55	DARBESTATUSX	Num	8			Final Study Status
56	DEATH_ALL	Num	8			Death by 2-year followup
57	DARBE_PRIM	Num	8			Bayley Cognitive Composite Score at 2 years (deaths imputed to lowest possible score)
58	ADJ_AGE_COGX	Num	8			Examiner Calculated Adjusted age at Bayley cognitive assessment
59	NDI3CAT_DARBE	Num	8			Neurodevelopmental Impairment at 2 years, moderate/severe levels combined (eTable 5)
60	DEATHNDI_DARBE	Num	8			Moderate/Severe NDI or death by 2 years
61	CP_ANY	Num	8			Any cerebral palsy (grade 1+) at 2 years
62	B3_LANGCS	Num	8			Bayley III language composite score at 2 years
63	B3_MOTCS	Num	8			Bayley III motor composite score at 2 years
64	FWEIGHTX	Num	8			Weight at follow-up in kg at 2 years

Num	Variable	Type	Len	Format	Informat	Label
65	FLENGTHX	Num	8			Recumbent length at follow-up in cm at 2 years
66	FHCX	Num	8			Head circumference at follow-up in cm at 2 years
67	Z_FWEIGHTX	Num	8			Z score for FU weight by WHO at 2 years
68	Z_FLENGTHX	Num	8			Z score for FU length by WHO at 2 years
69	Z_FHCX	Num	8			Z score for FU head circumference by WHO at 2 years
70	FAMILYID	Num	8			Family ID

Data Set Name: bp_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	BPDAT_INT	Num	8			BPDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	BPHIGHX	Num	8		11.	Highest Systolic BP
4	BPSITE_STD	Num	8		11.	BP Site (Coded Value)

Data Set Name: da_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	DADAT_INT	Num	8			DADAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	DASCAT_STDX	Num	8		11.	Study Drug Dispensed (Coded Value)
4	DAENDDAT_INT	Num	8			DAENDDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
5	DAWGHT	Num	8		6.3	Actual Infant Weight (kg)
6	DADOSE	Num	8		6.2	Actual Dose Dispensed (ug)
7	DESTRYDAT_INT	Num	8			DESTRYDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)

Data Set Name: *dr_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	DRSAMPID_STDX	Num	8		11.	Sample Identifier (Coded Value)
3	DRDOSEDAT_INT	Num	8			DRDOSEDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
4	DRROUTE_STD	Num	8		11.	Route of Study Drug (Coded Value)
5	DRSAMPDAT_INT	Num	8			DRSAMPDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
6	DRTYPE_STD	Num	8		11.	Sample Type (Coded Value)
7	DRFROZDAT_INT	Num	8			DRFROZDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
8	DRDEAMDAT_INT	Num	8			DRDEAMDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)

Data Set Name: *dv_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	PHARMDVYN_STD	Num	8		11.	Per pharmacy review, did any pharmacy violations or deviations occur for this infant? (Coded Value)
3	DVYN_STD	Num	8		11.	Did any protocol violations or deviations occur for this infant? (Coded Value)
4	DVSTTIM_INT	Num	8			DVSTTIM Interpolated (obscured as an interval in days from the reference date: Date of Birth)
5	DVTYP_STD	Num	8		11.	Type of Event (Coded Value)
6	CNSTLACK_STD	Num	8		11.	1 = Lack of consent (Coded Value)
7	WRONGDRG_STD	Num	8		11.	4 = Wrong study drug administered (Coded Value)
8	DRGNOTADMN_STD	Num	8		11.	6 = Study drug not administered per protocol (Coded Value)
9	NOIRONSUP_STD	Num	8		11.	7 = Iron supplementation not administered (IV or PO) > 7 days from previous dose (Coded Value)
10	DVTRANSFUS_STD	Num	8		11.	8 = Infant transfused outside transfusion protocol (included reasons and transfusion volume) (Coded Value)
11	DVOTHR_POOL_STD	Num	8			Other Violation: Codes 2, 3, 9, 10, or 11

Data Set Name: ie_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	IEYN_STD	Num	8		11.	IEYN Coded Value

Data Set Name: *is_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	ISFRSTDAT_INT	Num	8			ISFRSTDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	ISLASTDAT_INT	Num	8			ISLASTDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
4	ISCODE_STD	Num	8		11.	Iron Supp Codes (Coded Value)
5	ISTYPE_STD	Num	8		11.	Iron Type (Coded Value)
6	ISROUTE_STD	Num	8		11.	Route of Iron (Coded Value)
7	ISDOSEX	Num	8		5.1	Dose (mg/kg)

Data Set Name: *pv_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	PVOCCURYN_STD	Num	8		11.	Did any pharmacy violations or deviations occur for this infant? (Coded Value)
3	PVTYPE_STD	Num	8		11.	Type of Event (Coded Value)
4	UNMASKDYN_STD	Num	8		11.	Unmasked (Coded Value)
5	DRGNTPRYN_STD	Num	8		11.	Study drug not prepared per protocol (Coded Value)
6	INCORRDOSYN_STD	Num	8		11.	Incorrect study dose dispensed (Coded Value)
7	WRNGDRUGYN_STD	Num	8		11.	Wrong study drug dispensed (Coded Value)
8	DRGNTAVLYN_STD	Num	8		11.	Study drug not available; stock ran out (Coded Value)
9	OTHYN_STD	Num	8		11.	Other (Coded Value)
10	PVDAT_INT	Num	8			PVDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)

Data Set Name: rd_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	RDRNDTRT	Char	33	\$33.	\$33.	RDRNDTRT
2	SUBJECTID	Char	10			Internal id for the site (replaced with randomized identifiers)

Data Set Name: sc_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	SCENDDAT_INT	Num	8			SCENDDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	SCCMPLTYN_STD	Num	8		11.	Did the infant complete study drug as planned (until 35 completed weeks gestation, discharge, death or transfer to another hospital whichever comes sooner)? (Coded Value)
4	SCNTCMRSN_STDX	Num	8		11.	If SCCMPLTYN_STD = No, code reason (Coded Value)

Data Set Name: sd_biol.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	SDYN_STD	Num	8		11.	SDYN Coded Value

Data Set Name: *tf_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	TFDAT_INT	Num	8			TFDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
3	TFTESTNO	Num	8		11.	H&H Test (DRB05)
4	TFWGHTX	Num	8		6.3	Weight (kg)
5	TFVOLX	Num	8		6.1	Volume given (mL)
6	TFCODE_STDX	Num	8		11.	Transfusion Reason (Coded Value)

Data Set Name: *wd_biol.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJECTID	Char	10			Internal id for the subject (replaced with randomized identifiers)
2	WDYN_STD	Num	8		11.	Was the infant withdrawn from study participation at any time during the study period? (Coded Value)
3	WDDAT_INT	Num	8			WDDAT Interpolated (obscured as an interval in days from the reference date: Date of Birth)
4	WDSTATUS_STD	Num	8		11.	Select the withdrawal status appropriate for this infant: (Coded Value)